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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/227,881	01/11/1999	THAI D. NGUYEN	07425.0057	7578

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/227,881	NGUYEN ET AL.	
	Examiner	Art Unit	
	J. Douglas Schultz	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *79-81,92-96 and 98-143* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *79-81, 94, 96, 100, 102, 103, 106, 108, 109, 112, 114, 115, 118, 120, 121, 124, 126-143* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-12-2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 92,93,95,98,99,101,104,105,107,110,111,113,116,117,119,122,123 and 125.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 12, 2004 has been entered.

Status of Application/Amendment/Claims

Applicant's response filed March 12, 2004 has been considered. Rejections and/or objections not reiterated from the previous office action mailed August 13, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Claims 92, 93, 95, 98, 99, 101, 104, 105, 107, 110, 111, 113, 116, 117, 119, 122, 123, and 125 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 23, filed October 29, 2002.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants arguments regarding the non-entry of the amendment submitted after-final on November 13, 2003 have been noted, but are considered moot in view of its entry as a result of the presently filed RCE.

Withdrawal of Allowable Subject Matter

The indicated allowability of claims 94, 115, 118, and 120 is withdrawn in view of the reasoning set forth below. Rejections based on the newly cited reference(s) follow.

Claim Objections

Claim 131 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 131 is drawn to the full length SEQ ID NO: 3, while the claim from which it depends recites only fragments of SEQ ID NO: 3.

Response to Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 136 recites the limitation "wherein said fragment" in claim 133. There is insufficient antecedent basis for this limitation in the claim, because claim 133 eliminates the term fragment from claim 132 upon which claim 133 depends. Claim 133 narrows the scope of claim 132 to recite only the full length SEQ ID NO: 3.

Claim 137 recites the limitation "[T]he cell of claim 137". The claim must refer to an earlier claim.

Claims 79-81, 94, 96, 97, 100, 102, 103, 108, 109, 112, 114, 121, 124, and 126 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and is repeated for the same reasons of record as set forth in the Official action mailed February 25, 2003.

Claims 94, 115, 118, 120, and new claims 127-132, 134-138, and 140-143 are hereby added to this rejection, because the claim language therein recites "A...nucleic acid..comprising a...sequence of SEQ ID NO: 3...". Such language is interpreted to encompass any sequence or fragment of SEQ ID NO: 3. As explained in the rejection from the previous Office action and reiterated below, applicants are not considered to be in possession of the genus of fragments of SEQ ID NO: 3 that have a functional regulatory region, because one of skill would not envision the genus of any structure that would provide for a functional regulatory region.

As a first matter, applicants have traversed a reference to 35 U.S.C. § 101 in the present rejection under 35 U.S.C. § 112 first paragraph written description. Applicants have assumed that the reference to the 35 U.S.C. § 101 statute constituted a rejection under this statute, conclude that the scope and nature of the instant rejection has been changed, and finally assert that the finality of the previous Office action was improper.

In response, it is noted that the propriety of the finality of the previous Office action is officially moot by virtue of applicants' filing of a Request for Continued Examination. If applicants believe that finality was premature, applicants are referred to 37 C.F.R. § 1.181, and

M.P.E.P. §§ 706.07(c) and 1002.02(c) for a discussion of the proper mechanism for petitioning this finding.

However, in brief response, the context of the reference to 35 U.S.C. § 101 as actually written in the rejection under 35 U.S.C. § 112 first paragraph written description clearly does not support the conclusion discussed in footnote 1 of applicants response. The reference to 35 U.S.C. § 101 therein was cited to rebut applicants' allegation that in order to claim a genus of sequences by their function, "they need not identify and correlate functional regions of the claimed nucleic acids to meet the written description requirement where they have provided a precise definition, such as by structure and formula." Thus applicants appear to assert that such sequences do not require a function, as long as their structure is identified. It was merely pointed out that this assertion is erroneous and irrelevant, because without this basic relationship disclosed between structure and function, that the invention would not possess utility, let alone written description. Thus, it was indicated that "the specification must provide some link between structure and function under the guidelines of 35 U.S.C. 101, which applicants have disclosed as fragments retaining translational control activity over the subject TIGR protein." Thus, it is acknowledged that the required relationship identifying a utility for the contemplated molecules had been disclosed. This statement was used to set up the question of whether this disclosure adequately supports claims to a broad genus of molecules identified by a generic "functional regulatory region" (See claim 79).

Contrary to applicants assertions, nowhere has it ever been set forth that the claims failed to comply with 35 U.S.C. § 101, nor is one currently being maintained. Should applicants disagree, applicants are invited to point out with particularity by page and line number where it

was stated that any claims were so rejected. The finality of the previous Office action is therefore maintained as proper.

In regards to the rejection at hand, the claims have been amended such that they are now drawn to nucleic acids comprising fragments of SEQ ID NO: 3 that are between 15 and 250 nucleotides long and possess a "functional regulatory region". The specification identifies a number of such functional regulatory regions present within SEQ ID NO: 3, but does not provide any teaching that would allow one of skill to envision any other functional regions beyond those disclosed. However, in claiming the genus of any functional regulatory region, applicants claim language attempts to do just that, i.e. claim structures yet to be disclosed. One could not envision structures additional to those disclosed because the regulatory regions do not share a common core sequence, and in fact, vary substantially and unpredictably in sequence from one such region to another. Thus, the instant rejection is maintained on the grounds that while one of skill could envision fragments of SEQ ID NO: 3 that are between 15 and 250 nucleotides long, one of skill could not envision which of these fragments would retain a functional regulatory region. Accordingly, applicants are not considered to be in possession of the broad genus of any such molecules that retain a functional regulatory region, because one of skill could not be apprised as to what actually constitutes a functional regulatory region other than those disclosed.

Applicants assert throughout their arguments that the examiner has failed to apply proper standards for determining the adequacy of written description, because the instant specification supplies the specific nucleotide sequence of SEQ ID NO: 3, from which one can glean the structure of the claimed molecules, and further suggest that when this is combined with the

disclosure which identifies a number of functional regulatory regions, that adequate guidance has been provided.

This is not convincing. At issue is whether adequate description exists for fragments that retain the correlated activity (i.e. functional regulatory activity), not whether the whole of SEQ ID NO: 3 is adequately described. It is agreed that applicants have adequately described SEQ ID NO: 3. However, no common sequence or structure has been defined from the fragments of 15 to 250 nucleotides that are expected to retain some translational control over the expression of said protein in the specification such that one of skill would envision any new functional regulatory region heretofore unidentified. This is because functional regulatory regions do not share any significant homology or common core structures that would allow one of skill to predict or envision any other functional regulatory sequences. Such sequences are determined empirically. In the absence of any teaching as to common core structures or sequences that impart response element (i.e. functional regulatory region) activity, one of skill could not be apprised as to what structures beyond those already disclosed that have the claimed function.

While applicants have described a method of obtaining more such regions, it has been well established that a patent is not a hunting license, but a reward for a search well done. A screening method does not provide written description of the actual molecules. One of skill in the art would not have divined from the broad disclosure of a 6000 nucleotide sequence which actual fragments might retain such function. Applicant is not considered to have disclosed sufficient identifying characteristics of structure and/or function. Even though the identifying characteristics of a biomolecule may include a sequence or structure, such structures need to be correlated with their functions such that one of skill would be able to envision the members of

the genus. Applicants simply have not provided a sufficient and representative sample of structures that would allow one of skill to envision any common structure which provides for functional regulatory activity, and thus have not fully set forth the invention as claimed. Because the claimed fragments are described in the specification as those retaining translational control activity, and because applicants have not described a sufficient number of fragments that retain such a function, the rejection of record is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 79-81, 94, 96, 100, 102, 103, 108, 109, 112, 114, 115, 120, 121, 126, 127-132, 134, 135, 137, 138, 139, 140, 141 and 143 are rejected under 35 U.S.C. 102(b) as being anticipated by Becker *et al.*

The claims of the instant invention are drawn to nucleic acids comprising a fragment of SEQ ID NO: 3 that is between 15 and 250 nucleotides long and retain a functional regulatory region.

Becker *et al.* teach a nucleic acid in vectors and cells that comprise a glucocorticoid response element, which is a fragment of SEQ ID NO: 3. Therefore, Becker *et al.* teaches a nucleic acid comprising a fragment of SEQ ID NO: 3 that is between 15 and 250 nucleotides long and retains a functional regulatory region.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 127 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6 of prior U.S. Patent No. 5,861,497. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 103, 106, 108, 109, 112, 114, 115, 118, 120, 121, 124, 126, 132-135, and 138-143 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 5, 7, 8, 10, 11, 13, and 15 of U.S. Patent No. 5,606,043. Although the conflicting claims are not identical, they are not patentably distinct from each other

because the instant claims are drawn to cells and vectors containing SEQ ID NO: 3, which is the subject of claims 1, 2, 4, 5, 7, 8, 10, 11, 13, and 15 of U.S. Patent No. 5,606,043. Placing a known and patented sequence into vectors and cells is considered to be obvious.

Claims 103, 106, 108, 109, 112, 114, 115, 118, 120, 121, 124, 126, 132-135, and 138-143 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 6, 8, 9, 10 ,13, and 14 of U.S. Patent No. 6,150,161. Although the conflicting claims are not identical, they are not patentably distinct from each other because cells and vectors containing SEQ ID NO: 3, which is the subject of claims 5, 6, 8, 9, 10,13, and 14 of U.S. Patent No. 6,150,161. Placing a known and patented sequence into vectors and cells is considered to be obvious.

Claims 79, 94, 96, 100, 102, 103, 106, 108, 109, 112, 114, 115, 118, 120, 121, 126, 128, 129, 132, 133, 135, 136, 138, 139, and 141 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,861,497. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to fragments between 15 and 250 nucleotides of SEQ ID NO: 3 that have a functional regulatory region and may optionally be in vectors or cells, while the claims of U. S. Patent Number 5, 861, 497 are drawn to fragments between 15 and 250 nucleotides of SEQ ID NO: 3 with no claimed functional language. Thus the patented claims embrace the instant claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James Douglas Schultz, PhD

SEAN McGARRY
PRIMARY EXAMINER
1635